What is the relationship between alcohol consumption during lactation and the quality and quantity of breast milk available for the offspring?

Conclusion

Moderate, consistent evidence shows that when a lactating mother consumes alcohol, alcohol enters the breast milk and the quantity of milk produced is reduced, leading to reduced milk consumption by the infant.

Grade: Moderate

Overall strength of the available supporting evidence: Strong; Moderate; Limited; Expert Opinion Only; Grade not assignable For additional information regarding how to interpret grades, click here

Evidence Summary Overview

This conclusion is based upon the review of thirteen small studies examining the influence of alcohol consumption during lactation on the quality and quantity of milk available for the offspring. Six studies examined the effect of alcohol ingestion during lactation on quality (impact on physical properties or chemical composition) of breast milk produced. Seven within-subject design studies addressed the impact of alcohol consumption during lactation on quantity of breast milk produced or consumed.

Influence on quality of breast milk:

- Four studies evaluated **alcohol pharmacokinetics** in lactating women using a dose of 0.4g per kg and one study used a dose of 0.3g per kg alcohol. A prospective cohort study (N=23 Chinese women) (Chien et al, 2005) predicted time required for milk alcohol level to return to zero level was 175 minutes following consumption of approximately 0.3g per kg alcohol in a chicken soup flavored with sesame oil and rice wine. Pepino et al, 2007 found that blood alcohol concentration was significantly lower in lactating women when compared with non-lactating women. Mennella and Pepino, 2010 evaluated Breath Alcohol Concentration (BrAC) before and after pumping, and found that levels of BrAC were significantly lower during than after pumping. Pepino and Mennella, 2008 found that pumping before drinking significantly decreased blood ethanol concentration ($P<0.05$) and ethanol bioavailability ($P=0.05$)
- Two studies (Mennella JA, 1997; Mennella JA and Beauchamp GK, 1991) evaluated the influence of potential alterations in breast milk flavor and odor caused by alcohol consumption during lactation on infant breast milk intake. Results showed that short-term alcohol consumption by lactating women significantly increased the perceived intensity of the odor of their milk. One study found no suppression of sucking or intake in response to the ethanol-flavored milk. Rather, the infants consumed significantly more milk [Paired T (39df)=2.78; $P<0.008$] and sucked more [paired T (38df)=2.45; $P<0.019$] frequently when drinking the alcohol-flavored milk compared with the unaltered milk. The second study found that infants sucked more frequently during the first minute of feedings after alcohol consumption by their mothers (67.0±6.5 sucks, as compared with 58.4±5.9 sucks for feeding after the consumption of the non-alcoholic beverage; $P<0.05$), but they consumed significantly less milk (120.4±9.5ml vs. 156.4±8.2ml $P<0.001$) during the testing sessions in which mothers drank the alcohol beverage.

Influence on quantity of breast milk:

- Two within-subjects design studies evaluated **milk ejection response** before and after administration of different doses of alcohol. Chien YC et al, 2008 (neutral quality) reported significant inhibited milk-ejecting response in 23 Chinese women following consumption of a soup prepared with alcohol (average dose of 0.3g per kg body weight. Similarly, Cobo et al, 1973, evaluated 22 lactating women, finding that 1-2g per kg intake of alcohol significantly reduce milk ejection
- Three within-subjects design studies evaluated **breast milk intake of infants** after their mother ingested alcoholic beverages. Menella, 2001 and Menella and Beauchamp, 1993 found that infants consumed approximately 20-22% less milk after their mother had ingested 0.3g per kg dose of alcohol. With a similar dose

of maternal alcohol intake Menella, 1998 found that the amount of milk produced by the lactating mother was significantly reduced (9.3% ±4.1)

- Two studies evaluated the effects of alcohol on **hormonal responses** and milk yield over time. Menella and Pepino, 2008 found that alcohol consumption increased basal PRL levels ($P<0.0001$) and modified the PRL response to pumping ($P<0.0001$), but the directionality of the response depended on when pumping occurred along the blood alcohol concentration (BAC) curve. Menella et al, 2005 found that oxytocin levels significantly decreased, whereas prolactin levels and measures of sedation, dysphoria, and drunkenness significantly increased, during the immediate hours after alcohol consumption. In the short term, mothers may be more relaxed, but the hormonal milieu underlying lactation performance is disrupted, and in turn, the infant's milk supply is diminished.

Evidence Summary Paragraphs (13)

Influence on Quality

Pharmacokinetics

Chien et al, 2005 (positive quality), conducted a non-randomized trial to investigate the pharmacokinetics of alcohol in 23 Chinese lactating mothers after they consumed chicken soup flavored with sesame oil and rice wine (CSSR). Experimental findings were employed to estimate the potential ethanol dose to neonates and determine associated health risks. The target alcohol dosage was 0.3 g per kg. Milk and blood samples were collected at fixed time intervals from each subject following exposure to CSSR, and alcohol levels were determined. Blood alcohol level peaked at 20 minutes after exposure to CSSR and decreased almost linearly thereafter. Alcohol in milk reached a plateau roughly at 20-40 minutes after exposure to CSSR and then decreased. Alcohol pharmacokinetics among subjects varied widely. The coefficients of variation in subject alcohol concentrations were 16.5-46.2% (mean=30.0%) for blood and 32.8-57.6% (mean=44.4%) for milk. Mean maximal alcohol concentration in blood (30.2±5.0mg/dL) was achieved at 23.5±7.6 minutes and in milk (31.6±10.3mg/dL) at 31.7±12.7 minutes. Potential infant doses were 3.0-58.8mg (mean=13.4mg), and the predicted time required for milk alcohol level to return to zero level was 175 minutes. The acute health risks for infants exposed to alcohol through their mothers' milk under the current exposure scenario are low (hazard index<0.2).

Pepino et al, 2007 (positive quality), conducted a within-subjects design study to test the hypothesis that lactation alters alcohol pharmacokinetics. Subjects included 20 lactating women who were exclusively breastfeeding a two- to five-month-old infant and two control groups of non-lactating women. The first control group consisted of nine women who were exclusively formula-feeding similarly aged infants, whereas the other consisted of 15 women who had never given birth. Women drank a 0.4g/kg dose of alcohol following a 12-hour overnight fast during one test session (fasted condition) or 60 minutes after consuming a standard breakfast during the other (fed condition). Blood alcohol concentration (BAC) levels and mood states were obtained at fixed intervals before and after alcohol consumption. Under both conditions, the resultant BAC levels at each time point were significantly lower and the area under the blood alcohol time curve were significantly smaller in lactating women when compared with the two groups of non-lactating women. There were no significant differences among the three groups of women in the stimulant effects of alcohol. However, lactating women did differ in the sedative effects of alcohol when compared with nulliparous but not formula-feeding mothers. That is, both groups of parous women felt sedated for shorter periods of time when compared with nulliparous women. The authors concluded that the systemic availability of alcohol was diminished during lactation. However, the reduced availability of alcohol in lactating women did not result in corresponding changes in the subjective effects of alcohol.

Mennella JA and Pepino MY, 2010 (positive quality), conducted a randomized control trial (RCT) to determine whether breast pumping works independently of the physiological and metabolic changes that accompany lactation. Twelve women were tested during two reproductive stages: When they were exclusively breastfeeding three- to five-month-old infants and then again several months after lactation had ceased. Subjects were randomly assigned to one of two groups that differed in the timing of breast pumping relative to drinking a 0.4g/kg dose of alcohol: One group breast pumped 0.6 hours after drinking (PA) and the other pumped one hour before drinking (PB). For each reproductive stage, subjects were tested on two separate days, consuming a standardized meal one hour before drinking during test day and remaining fasted during the other. Breath alcohol concentrations (BrAC) and temperature readings were obtained before and at fixed intervals after drinking. Pumping before drinking significantly decreased BrAC during both reproductive stages, whereas pumping after drinking resulted in different BrAC time curves during lactation when compared with after lactation. Levels of BrAC were significantly lower during the descending phase of the time curve during than after lactation. The interactions between pumping and reproductive stage were most apparent during fed condition.

Pepino MY and Mennella JA, 2008 (positive quality), conducted a randomized, within-subject design study to evaluate two hypotheses. First, that breast pumping contributes to the previously observed decrease in ethanol bioavailability in lactating women. Second, that the effects of breast pumping are more pronounced when ethanol is consumed after a meal. The within-subject factor was test condition (fed or fasted) and the between-subject factor was experimental group (pumped before, PB; pumped after, PA). Those randomly assigned to the PB group (N=8) breast pumped one hour before drinking, whereas those assigned to the PA group (N=8) breast pumped 0.6 hour after drinking. Pumping before drinking significantly decreased blood ethanol concentration ($P<0.05$) and ethanol bioavailability ($P=0.05$). The effects were more pronounced when ethanol was consumed after a meal.

Influence on Breast Milk Flavor or Odor

Mennella JA, 1997 (positive quality), conducted an RCT to determine whether diminished milk intake by infants of lactating women who consumed alcohol was due to infants responding to the altered flavor of the milk. Forty women and their infants were recruited from the Women, Infant and Children program in Philadelphia. Mothers expressed approximately 130ml of milk (mean=127.2±4.9), and divided into two equal aliquots. One aliguot remained unaltered and the other was flavored with 32mg ethanol/dL-the average concentration detected in human milk approximately one hour after lactating women drank an acute does (0.3g per kg) of alcohol. The evaluation consisted of a two-bottle test preference composed of four, 60 seconds. trials in which the mother's milk flavored with alcohol was alternated with the control in an ABBA or BAAB design (data were obtained for the first two trials for only nine of the 40 infants because there was not enough milk remaining in the bottles to complete the session). Attached to the nipple of each bottle was a transducer that responded to pressure changes produced by the infant's suckling. There was not suppression of sucking or intake in response to the ethanol-flavored milk. Rather, the infants consumed significantly more [Paired $T(39df)=2.78$; $P<0.008$] and sucked more [paired $T(38df)=2.45$; $P<0.019$] frequently when drinking the alcohol-flavored milk compared with the unaltered milk. These findings indicate that infants can readily detect the flavor of alcohol in mother's milk but that the decreased in consumption is apparently not due to the infants rejecting the flavor of alcohol on their mothers' milk.

Mennella JA and Beauchamp GK, 1991 (positive quality), conducted a randomized crossover study to investigate whether the ingestion of alcohol by lactating women altered the odor of their milk and whether exposure to a small amount of alcohol on the mother's milk had immediate effects on the behavior of the infant. Twelve lactating women and their infants were tested on two days separated by an interval of one week. On each testing day, the mother drank either orange juice or orange juice containing a small quantity of ethanol (0.3g per kg of body weight). Ethanol content of milk was analyzed in additional samples and a panel of adults determined whether the difference in the odor of the milk was detectable after alcohol consumption. The infants were weighed before and after nursing to assess the amount of milk they ingested, and their behavior during breastfeeding was monitored by videotape. Results showed that short-term alcohol consumption by lactating women significantly increased the perceived intensity of the odor of their milk, peaked 30 minutes to one hour after consumption and decreased thereafter. Alteration in the milk's odor closely paralleled the changes in ethanol concentration (mean range, 0 to 6.9mmol per liter). The infants sucked more frequently during the first minute of feedings after alcohol consumption by their mothers (67.0±6.5 sucks, as compared with 58.4±5.9 sucks for feeding after the consumption of the non-alcohol beverage; $P<0.05$), but they consumed significantly less milk (120.4±9.5ml vs. 156.4±8.2ml $P<0.001$) during the testing sessions in which mothers drank the alcohol beverage.

Influence on Quantity

Changes in Milk Yield/Infant Intake

Chien YC et al, 2009 (positive quality), conducted a within-subjects design study to examine whether ethanol exposure influences selected constituents in a maternal blood and milk, as well as lactation performance. Twenty-three lactating Chinese mothers were examined on two occasions, separated by a week. The target alcohol dosage was 0.3g per kg body weight. Milk and blood samples were collected prior to consumption of a traditional soup containing alcohol [chicken flavored soup with sesame oil and rice wine (CSSR)], and at 120 and 150 minutes, respectively, after consumption. Differences in concentrations oftriacylglycerol (TAG) insulin, and lactate levels in maternal blood were statistically significant ($P<0.05$; paired T test) between CSSR and control groups, 150 minutes after soup consumption. Alcohol also affected milk composition and its nutritional status, particularly total protein, TAG, fatty acid, β-hydroxybutyrate, and lactate levels. The CSSR intake significantly affected TAG and lactate levels in milk ($P<0.05$; paired T test) at the end of the experiment. The time for the first milk droplet to be ejected was significantly longer in the CSSR group ($P<0.05$), indicating that the milk-ejecting reflex is inhibited. Comparing both groups, differences in milk volume was not statistically significant (NS).

Cobo et al, 1973 (neutral quality), conducted a non-randomized, within-subjects design study to evaluate milk-ejection response before and after administration of different doses of ethanol in 38 lactating women from the US. The magnitude of the milk-ejection response was estimated by measuring planimetrically the area under the pressure tracings during each suckling period, before and after ethanol intake. Ethanol in doses of 1g per kg did NS reduce the response, but after administration of 1-2g per kg of ethanol a significant reduction of the milk-ejecting response was observed. This inhibition appeared to be dose dependent.

Mennella JA, 2001 (positive quality), conducted a non-randomized, within-subjects design study (controlling for time of day) to test the hypothesis that infants would compensate for the diminished milk intake if their mothers then refrained from drinking alcohol. Twelve exclusively breastfed infants and their mothers in the US were tested on two days separated by one week. Each woman drank a 0.3g per kg dose of alcohol in orange juice on one testing day and orange juice alone on the other. The infants' behaviors were monitored for the next 16 hours, the first four hours of monitoring on each test day occurred at the Monell Center. Infants consumed approximately 20% less breast milk (paired T [11df]=2.35; P=0.04), but breastfed similar number of times (paired T [11df]= -0.00; P=1.00] during the first four hours after exposure to alcohol, compared with the control condition. They then compensated for diminished intake during the eight- to 12-hour exposure (paired T [11df]= -2.13; P=0.05]. This compensation appears to be due, in part, to the increased numbers of breastfeeding that occurred during the eight-to 12-hour post-exposure (paired T [11df]= -2.24; P=0.04.

Mennella JA and Beauchamp GK, 1993 (positive quality), conducted a within-subjects design study to examine if beer consumption by 12 US nursing women altered the sensory qualities of their milk and the behavior of their infants during breast-feeding in the short term. Women had 0.3g per kg of body weight dose of alcohol during the testing day and non-alcoholic beer during the control day. All of them were used as their own control (tested on two days, separated by a week). The infants consumed significantly less milk during the four-hour testing sessions in which their mothers drank alcoholic beer compared to when the mothers drank non-alcoholic beer, 149.5±13.1ml, compared to the session in which she drank the non-alcoholic beer, 193.1±18.4ml, paired T (10df)= -2.47; P=0.03. This decrease in milk intake was not due to a decrease in the number of times babies fed. Although the infants consumed less of the alcohol-flavored milk, the mothers believed their infants had ingested enough milk. The amount of milk expressed by each mother did not differ on the two testing days (non-alcoholic vs. alcoholic beer: 47.4±3.1ml vs. 50.0±4.2ml, paired T [10df]; P NS).

Mennella JA, 1998 (positive quality), conducted a non-randomized, within-subjects design to test the hypothesis that maternal alcohol consumption decreases the amount of milk available to the infant and alters milk composition in the short term. Timeline follow-back questionnaire for the mothers to record number, types, and frequency of alcohol consumption. To this end 22 US lactating women were tested on two days separated by one week (±2 days), and they expressed milk from both breasts simultaneously by using an electrical breast pump. The entire collecting procedure was repeated two hours later (baseline), after which the mother drank either a 0.3g per kg dose of alcohol in orange juice or an equal volume of orange juice alone within a 15-minute period. There was NS difference in the amount of milk pumped at baseline [paired T(21df)= -1.06; P=0.30], but mothers pumped significantly less milk two hours after consumption of the alcoholic beverage when compared with the amount pumped two hours after consuming the control beverage {paired T(21df)=2.45; P=0.02]. Although there was no difference in the energy content of the milk, maternal alcohol consumption significantly reduced the amount of milk produced by the lactating mother (9.3% (±4.1) less milk). This decrease in milk production tended to be apparent during the first five minutes of pumping during the two-hours post-consumption collection period [control vs. alcohol: 53.6±5.2 vs. 50.1± ml; paired T(21df)=1.54; P=0.13)].

Mennella JA and Pepino MY, 2008 (positive quality), conducted a 2x2 within-subject design, double-blind, four-session study to test effects of alcohol on prolactin (PRL) responses and milk yield over time. In 13 lactating mothers, the two within-subject factors were beverage condition (control or 0.4g per kg dose of alcohol) and pumping condition (pumping occurred at fixed intervals once or twice during the 5.3-hour session. Plasma PRL, blood alcohol concentrations (BAC) and milk yield were measured. Alcohol consumption increased basal PRL levels (P<0.0001) and modified the PRL response to pumping (P<0.0001), but the directionality of the response depended on when pumping occurred along the BAC curve. Pumping enhanced PRL response when it occurred during the ascending BAC limb but blunted the response when it occurred during the descending limb, providing evidence that the effects were transient and of a biphasic nature. The slower alcohol was metabolized, the greater the relative PRL response to breast pumping (P<0.05). The dynamics of the PRL response between pumping sessions were also altered if women drank. If women pumped within an hour after drinking alcohol, the PRL response during the next pumping some 1.5 hours later was delayed by a few minutes. BAC levels ascended during the first hour, reaching peak levels of 0.60±0.03g per L at

around 42 minutes post-consumption during the two sessions in which women drank alcohol. For the next 2.6 hours, BAC levels steadily descended reaching levels of 0.15±0.02g per L at the time the sessions ended. On average, the alcohol disappearance rate was 0.14±0.01g per L per hour. There were NS differences in the BAC time curve during the two test session in which subjects drank alcohol. Milk yield was significantly lower after drinking alcohol but such deficits were NS related to PRL or the speed at which alcohol was eliminated. Effects of alcohol on suckling-induced PRL were biphasic in nature, but could not explain the deficits in lactational performance. Such findings provide further evidence that the dynamic changes in neuroendocrine state are integrally involved in alcohol's effects over time and underscore the complexity of lactation.

Mennella et al, 2005 (positive quality), conducted a randomized, within-subjects design study to test the hypothesis that alcohol consumption affects hormonal response in lactating women (N=17). Women consumed a 0.4g per kg dose of alcohol in orange juice during one test session and an equal volume of orange juice during the other. Changes in plasma prolactin, oxytocin, and cortisol levels during and after breast stimulation, lactational performance and mood states were compared under the two experimental conditions. Oxytocin levels significantly decreased, whereas prolactin levels and measures of sedation, dysphoria, and drunkenness significantly increased, during the immediate hours after alcohol consumption. Changes in oxytocin were related to measures of lactational performance such as milk yield and ejection latencies, whereas changes in prolactin were related to self-reported measures of drunkenness. Although alcohol consumption resulted in significantly higher cortisol when compared with the control condition, cortisol levels wereNS correlated with any of the indices of lactational performance or self-reported drug effects. In conclusion, recommending alcohol as an aid to lactation may be counterproductive. In the short term, mothers may be more relaxed, but the hormonal milieu underlying lactational performance is disrupted, and, in turn, the infant's milk supply is diminished.

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Author, Year, Study Design, Class, Rating	Study Subjects	Measurements	Treatment	Key Outcomes
Chien YC et al 2009 Study Design: Non-Randomized Crossover Trial Class: C Rating:	Subjects recruited from gynecology and obstetrics clinics at Taipei Medical University Wan-Fang Hospital. N=23. Each subject tested on two occasions separated by a week.	Breast milk alcohol analysis within the mid-point (135 minutes). Breast milk composition. Time for ejection of the first milk droplet. Total milk volume.	Target alcohol dosage of 0.30g per kg body weight achieved by administering ~8ml of traditional soup (CSSR) per kg of body weight. Control: Non-alcoholic soup. Compliance measure by three-day dietary records.	150 minutes after soup consumption, concentrations of TAG, insulin and lactate levels in maternal blood were statistically significant (P<0.05; paired T test) between CSSR and control groups. CSSR intake affected milk. Composition and its nutritional status, particularly total PRO, fatty acid, β-hydroxybutyrate and lactate levels. CSSR intake significantly affected TAG and lactate levels in milk (P<0.05; paired T test) at end of experiment. Time for the first milk

				droplet to be ejected was significantly longer in CSSR group ($P<0.05$). Comparing both groups, milk volume was NS.
Chien YC, Liu JF et al, 2005 Study Design: Non-randomized trial Class: C Rating: 	N=23 Chinese women. Subjects recruited from gynecology and obstetrics clinics at Taipei Medical University Wan-Fang Hospital. Age: 24.5±3.4 years. Height: 158.8±6.5cm. Weight: 62.5±9.6kg.	Alcohol levels in milk and blood at 10, 20, 30, 40, 60 and 90 minutes. Milk volume at 120 minutes post-exposure to "chicken soup flavored with sesame oil and rice wine" (CSSR). Mean time required for milk alcohol levels to return to zero level (defined as half the analytical detection limit) using the equation: Milk alcohol level= -0.193 x time+35.1 (r^2=0.999, $P<0.05$). Mean blood ethanol disappearance rate using the equation: Blood alcohol level= -0.15 x time+31.9 (r^2=0.994, $P<0.05$). Infant risk associated with alcohol exposure through breast milk, using hazard index (estimated worst-case infant dose divided by a reference dose).	CSSR alcohol level varies, for this study it was determined to be 40.6±1.8mg per ml. Target alcohol dosage of 0.3g per kg of body weight achieved by administering ~8ml of soup for each kg of subject body weight.	Mother's blood alcohol levels peaked at 20 minutes after ingestion of CSSR and ↓ almost linearly to zero level after roughly three hours. Milk alcohol levels peaked at around 20-40 minutes and ↓ linearly thereafter. At 135 minutes post-CSSR consumption, alcohol concentrations in milk were 9.0±5.2mg per dL, significantly ↑ than the pre-CSSR consumption level. Mean time required for milk alcohol levels to return to zero level was estimated at ~175 minutes. Mean blood ethanol disappearance rate was 90mg per L per hour. Average peak time for milk alcohol was 31.7±12.7 minutes post-exposure. Average peak time for blood alcohol was 23.5±7.6 minutes, occurring statistically faster than in milk, $P<0.05$. Mean maximal milk alcohol concentration in this study was

				31.6±10.3mg per dL, and NS different from the mean maximal BAC (30.2±5.0mg per dL). Correlation coefficients between blood and milk alcohol levels varied for each individual: (range, 20.96 to 0.99; median, 0.79; mean, 0.62). Six of the correlation coefficients (subjects one, four, 13, 14, 16, 22) reached significant levels. Correlation coefficient between blood and milk alcohol levels based on pooled data from all subjects was 0.769.
Cobo E, 1973 Study Design: Non-randomized trial Class: C Rating:	Study from the Unit of Physiology of Reproduction, Division of Health, del Valle University, Colombia. N=38. All subjects used as their own control.	Mammary response to milk ejection by measuring planimetrically the area under pressure tracing during each suckling period, before and after ethanol intake.	Ethyl alcohol doses expressed in weight per volume. Doses divided into four groups (per kg): • 0.1-0.49 • 0.5-0.99 • 1.0-1.49 • 1.5-1.99g. Two subjects received 2.0g per kg.	Results by doses of ethanol: 0.147-0.450g per kg did not produce inhibition of the milk-ejecting reflex 0.521-1.464g per kg ↓, but not statistically difference 1.583-1.924g per kg ↓, statistically different.
Menella JA and Pepino MY, 2008 Study Design: Randomized control trial. 2x2 within-subject quasi-randomized trial Class: A	N=16. Study based on Pepino et al, 2007. Subjects recruited from the Philadelphia area.	Blood ethanol concentrations (BECs). N=9; five in group PA (pumped after) and four in group PB (pumped before) were exclusively breastfeeding. N=7; three in group PA and four in group PB supplemented	Subjects drank 0.4g per kg dose of OH mixed with a non-caloric juice.	Significant Δ in BECs over time (P<0.001) and significantly dependent on timing of breast pumping (main effect of group: P<0.05;) and on whether ethanol was consumed before or after a meal (main effect of condition: P<0.001). During the fed

Rating:		breastfeeding with formula or baby foods no more than once a day.		condition, BEC levels significantly ↓ (P<0.001) and tended to peak later (P=0.06). Women who pumped before drinking (group PB) had lower peak BECs (P=0.01) and ↓ systemic availability of ethanol. Those who did not breast pump until 0.6 hours after drinking (group PA) eliminated ethanol faster.
Menella JA and Pepino MY, 2010 Study Design: Randomized Controlled Trial Class: A Rating:	Lactating women. N=12 (Six Caucasian, four African American, and two other/mixed race/ethnic groups). Age: 33.0±1.2 years.	Each woman was tested during two reproductive stages: 1) Exclusively breastfeeding (during lactation) 2) After lactation had ceased (after lactation), on two days separated by one week. Groups evaluated: 1) Pumping Before lactation (PB) breast pumped an hour before drinking 2) Pumping After lactation (PA) begin pumping 0.6 hour after alcohol consumption. Conditions evaluated: 1) Fed condition 2) Fasted condition one hour later of drinking a 0.4g per kg dose of alcohol 3) BrAC (Breath Alcohol	Alcohol dose=0.4g per kg.	Elimination rates were faster during fed (0.12±0.01) than fasted (0.09±0.01, F[1, 7]=100.8, P<0.001) condition. Significant interactions: Reproductive stage by time (F[14,140]=3.67, P<0.0001) and condition by time (F[14,140]=21.95, P<0.0001), and three-way interactions: Food condition by group and time (F[14, 140]=2.10, P=0.015) and reproductive stage by group and time (F[14,140]=7.67, P<0.0001) for the BrAC time curve. Fed and fasted conditions, in both reproductive stages significantly interacted with group and time (fed condition: F[14, 140]=2.86, P<0.001; fasted condition: F14,140]=5.93, P<0.0001). No differences observed

		Concentration) 4) Alcohol elimination rate (R), expressed as amount of alcohol eliminated per kg per hour calculated as R=β60/body weight.		between during and after lactation staged for group PB. Group PA had ↑ BrAC levels at time 25-35 minutes and ↓ BrAC levels at time 65, 85, and 105 minutes. Differences in BrAC between PA and PB groups were only observed in one time-point. PA BrAC levels were ↓ at 45 minutes during lactation, and ↑ at 25 minutes after lactation when compared with PB.
Mennella JA and Beauchamp GK, 1991 Study Design: Randomized Controlled Trial Class: A Rating: 	Subjects recruited from University of Pennsylvania area and from local La Leche groups. N=12. Age: 21 to 38 years (median 30 years). Infants: Eight girls, four boys Age: 25 to 216 days (median 120 days) All participants were used as their own control.	Babies' weight before and after breastfeeding. Volume (ml) of milk consumed estimated by dividing the weight of milk consumed by 1.031. Babies videotaped after breastfeeding. Odor of the milk by a sensory panel of 17 adults.	Testing day: 0.3g per kg of body weight dose of alcohol in orange juice. Control day: Orange juice alone.	Estimated dose of alcohol ingested by infants, taking into account the body weight of each infant, was 1.6 to 9.9mg per kg (mean 5.1±0.8 (3.3% of the maternal dose). Infants consumed significantly ↓ milk during the three-hours testing session in which their mothers drank alcohol (120.4±9.5ml vs. 156.4±8.2ml, paired T(11df)= -4.69, P<0.001). NS difference in number of feedings (control vs. alcohol: 2.5±0.2 vs. 2.2±0.2, paired T[11df]=1.91, P=NS). NS difference in total length of time during which infant was attached to the nipple (control vs. alcohol:

				28.6±7.7 vs. 28.2±7.3 minutes, paired T [11df]=0.15, P=NS). Infants sucked significantly more frequently during first few minutes of feedings on the day their mothers consumed the alcohol [F(8,1 df)=12.11, P<0.008]; the videotapes of three infants were not clear to detect frequency of sucking. However, NS difference in total number of sucks on the two days of testing [control vs. alcohol: 856.7±103.4 vs. 877.2±102.3, T (8df)=0.23, P=NS] NS difference in total amount of time infants slept during the three hours testing sessions (control vs. alcohol: 65.10±10.96 vs. 62.97±12.04 minutes, paired T [11df]=0.15, P=NS) or for remainder of the day until child awoke the next morning (14.45 ±1.71 vs. 13.47±1.76 hours, paired T [11df]=1.18, P=NS). Number of times infants slept ↑ on days when mothers consumed alcohol (6.6 ±0.7 vs. 7.8±0.9, paired T [11df]= -2.31, P<0.05).
Mennella JA, 1997 Study Design: Randomized trial	Subjects recruited from ads in local newspapers and from WIC Centers (Philadelphia). N=40.	Sucking responses recorded and measured using a device and computer software (Maone and colleagues 1992).	Evaluation consisted of a two-bottle test preference composed of four, 60-second trials in	Infants consumed ~20% ↓ breast milk (paired T [11df]=2.35; P=0.04), but breastfed similar number of times

Class: A Rating:		Timeline follow-back questionnaire for mothers (to record number, types and frequency of alcohol consumption).	which mother's milk flavored with alcohol [with 32mg ethanol per dL; the average concentration detected in human milk ~one hour after lactating women drank an acute dose (0.3g per kg) of alcohol] was alternated with the control in an ABBA or BAAB design.	[paired T (11df)= -0.00; P=1.00] during the first four hours after exposure to alcohol, compared with control condition.
Mennella JA, 1998 Study Design: Non-randomized crossover trial Class: C Rating:	Subjects recruited from ads in local newspapers and from WIC Centers in Philadelphia. N=22. Subjects used as their own control.	At baseline and post-consumption collection periods: Latency to eject (amount of time for first droplet of milk to be ejected) Milk yield or volume of milk expressed for each breast within each five-minute period Timeline follow-back questionnaire for mothers (to record number, types and frequency of alcohol consumption) Caloric and fat content of the milk.	Testing day: 0.3g per kg of body weight dose of alcohol in orange juice. Control day: Orange juice alone.	Mothers pumped significantly ↓ milk two hours after consumption of alcoholic beverage when compared with amount pumped two hours after consuming control beverage [paired T(21df)=2.45; P=0.02.
Mennella JA, 2001 Study Design: Non-randomized crossover trial Class: C Rating:	Subjects recruited from ads in local newspapers and from WIC Centers (Philadelphia). N=12. Subjects used as their own control.	Babies' weight after breastfeeding Babies videotaped after breastfeeding Volume (milliliters) of milk consumed estimated by dividing the weight of milk consumed by 1.031.	Testing day: 0.3g per kg of body weight dose of alcohol in orange juice. Control day: Orange juice alone.	Infants consumed ~20% ↓ breast milk (paired T [11df]=2.35; P=0.04), but breastfed similar number of times [paired T (11df)= -0.00; P=1.00] during first four hours after exposure to alcohol, compared with control condition.

Mennella JA, Beauchamp GK, 1993 Study Design: Randomized crossover study Class: A Rating:	Subjects recruited from the Philadelphia area. N=12. All subjects used as their own control (tested on two days, separated by a week).	Babies' weight after breastfeeding. Babies videotaped after breastfeeding. Volume (ml) of milk consumed estimated by dividing the weight of the milk consumed by 1.031.	Testing day: 0.3g per kg of body weight dose of alcohol. Control day: Equal volume of non-alcoholic beer. Half of women drank alcoholic beer during first session and non-alcoholic during second session. Estimated alcohol ingested by infant: 18.6-66.7mg (mean 43.1±5.2) or 2.3-8.4mg per kg or 0.8-2.8 % of the maternal dose (300mg per kg).	Infants consumed significantly ↓ milk during the four-hour testing sessions in which their mothers drank alcoholic beer compared to when mothers drank non-alcoholic beer, 149.5±13.1ml, compared to the session in which she drank nonalcoholic beer, 193.1±18.4ml, paired T (10df)= -2.47, P=0.03. Amount of milk expressed by each mother did not differ on the two testing days (non-alcoholic vs. alcoholic beer: 47.4±3.1ml vs. 50.0±4.2ml, paired T [10df]; P=NS).
Mennella JA, Pepino MY & Teff K 2005 Study Design: randomized crossover trial Class: A Rating:	Subjects recruited from the Philadelphia area. N=17. Subjects used as their own control.	Plasma prolactin, oxytocin and cortisol levels during and after breast stimulation, lactational performance and mood states. Blood alcohol concentrations (BAC) by having subject breath into an Alco-Sensor III.	Treatment: 0.4g per kg dose of alcohol. Control: No alcohol intake.	Significant interaction between condition and time on oxytocin levels (F[15,240df]=1.83; P=0.03). Significant interaction between condition and time on prolactin plasma levels (F[15,240df] =3.31; P=0.001). Significant effects of condition (F[1,16df]=5.91; P=0.03) and time (F[15,240df]=4.39; P=0.001). BAC peaked ~43-51 minutes after alcohol consumption and ↓ thereafter.

Pepino MY and Mennella JA, 2008 Study Design: Retrospective Cohort Study Class: B Rating:	Subjects recruited from the Philadelphia area. N=13. 2x2 within-subject design, double-blind.	Blood alcohol concentration (BAC). Beverage condition (control or 0.4g per kg dose of alcohol). Pumping condition (pumping occurred at fixed intervals once or twice during the 5.3-hour session).	Treatment: 0.4g per kg dose of alcohol. Control: No alcohol intake.	BAC levels ↑ during first hour, reaching peak levels of 0.60±0.03g per L at around 42 minutes post-consumption. On average, alcohol disappearance rate was 0.14±0.01g per L per hour. Significant effect of beverage condition on lactational performance (F1,11df)=8.74; P=0.01). Women expressed significantly ↓ milk during sessions in which they drank the alcoholic beverage. NS differences in fat content of milk expressed (F[1,11]=0.40; P=0.54).
Pepino MY, Steinmeyer AL et al, 2007 Study Design: Non-randomized trial with concurrent controls Class: C Rating:	Subjects recruited from the Philadelphia area. Three groups of women were compared: • Lactating (N=20) • Formula-feeding (N=9) • Nulliparous (N=15).	BAC by breathing into a fuel-cell sensor analyzer. Using Mumenthaler et al, 1999: Time-to-peak BAC Peak BAC disappearance rate (β60) Total amount of OH eliminated per hour (b60) was calculated by: b60=β60xTBW/Bw (equation not validated in lactating women) Alcohol eliminated rate (R)=β60/body weight.	Subjects drank 0.4g per kg dose of OH mixed with a non-caloric juice.	BAC time curves in lactating, formula-feeding and nulliparous women under the fed and fasted conditions showed significant main effects of reproductive state on BAC levels [F(2, 41)=4.98; P<0.025], peak BAC [F(2, 41)=4.8; P<0.025] and blood alcohol time curve (AUC) [F(2,41]=5.3; P<0.01). NS differences between groups in time to reach peak alcohol levels (P=0.25), BAC levels, and peak BAC levels significantly ↓ and AUCs significantly smaller in lactating women, when

				compared with both groups of non-lactating women. NS differences in β60, b60 or R among the groups (all P>0.50).

Research Design and Implementation Rating Summary
For a summary of the Research Design and Implementation Rating results, click here.

Worksheets

Chien YC, Huang YJ, Hsu CS, Chao JC, Liu JF. Maternal lactation characteristics after consumption of an alcoholic soup during the postpartum 'doing-the-month' ritual. *Public Health Nutr.* 2009;12(3):382-8. Epub 2008 Apr 22.

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